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Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER	
COOK, REBECCA	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 17

Application Number: 10/083,565
Filing Date: February 27, 2002
Appellant(s): CHI ET AL.

Matthew T. Latimer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 8, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 7-9, 12, 16, 20, 21 and 17-10, 22 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,245,805 Broder et al. 6-2001

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9, 12 and16-22 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,245,805 (Broder et al.).

Broder et al discloses (col. 9, lines 7-12) that docetaxel ("heretofore administered only parenterally") is useful for treating hepatocellular carcinoma and liver metastases (col. 15, line 43). Broder additionally discloses that docetaxel is commercially available in parenteral form for use in a human (col. 10, lines 17-18). Broder et al further states that the dosage is from "20-1000 mg/cm^2, based on body surface area, with said daily administration continued for 1-4 consecutive days each 2-3 weeks" (col. 17, line 66 through col. 18, line 2).

Instant dependent claims differ over Broder et al in reciting specific types of carcinomas (claims 8-9), type of administration (claim 12), use of additional agent or radiation (claims 13-15). Other dependent claims recite specific doses of docetaxel and duration of treatment (claims 17-22).

However, no unobviousness is seen in the instant dependent claims, since hepatocellular carcinoma would include the carcinomas recited in claims 8-9; parenteral administration would include intravenous infusion; it is well known in the cancer art to use more than one agent and radiation to treat cancer. Furthermore, the dosage ranges recited in claims 17-19 and the frequency of administration recited in claims 21-22 are included in the dosage range and frequency disclosed by Broder et al. Additionally, once a method of use of a compound is known it is within the skill of the artisan to determine the optimum dosage and frequency of administration.

Because of different embodiments in the disclosure it is the opinion of the Examiner that there are not enough blaze marks to conclude that the invention of claim 7 is anticipated. There is no specific embodiment that would lead one of ordinary skill to conclude that Broder et al anticipates the instant invention. In re Baird, 29 USPQ2nd 1550.

(11) Response to Argument

Appellants argue that Broder et al only shows treatments of hepatocellular carcinoma with oral administration and that the instant claims do not recite oral co-administration of docetaxel and cyclosporin as required by Broder et al. Appellants further argue that one of ordinary skill in the art would not be motivated to use docetaxel by itself because Broder et al teach that it is ineffective.

This is not persuasive. Broder et al disclose that docetaxel has previously been used parenterally and that in order to be get sufficient absorption in order to

use it orally, it should be administered with cyclosporin. Broder et al does not teach that docetaxel should not be used parenterally. Broder et al does teach that there are situations in which it might be desirable to use it orally.

Appellants additionally argue that the data in Broder et al do not show that paclitaxel administered with cyclosporin is present in an amount sufficient to treat hepatocellular carcinoma or that it can be localized to the liver. This is not persuasive, since the instant claims recited docetaxel and not paclitaxel.

Appellants further argue that Broder et al do not show that docetaxel can be administered in an amount sufficient to treat hepatocellular carcinoma. This is not persuasive. Broder et al discloses that docetaxel can be used to treat hepatocellular carcinoma and a dosage range that includes the instant range. Furthermore, once a method of use of a compound is known it is within the skill of the artisan to determine the optimum dosage and frequency of administration.

Appellants further argue that the oral doses disclosed by Broder et al would not suggest the appropriate does for intravenous administration or provide a reasonable expectation that the doses disclosed by Broder et al would be appropriate for intravenous administration of docetaxel to treat hepatocellular carcinoma. This is not persuasive. Broder et al (col. 15, lines 11-12) discloses that the blood level of paclitaxel reached after oral doe is comparable to that achieved with IV infusion. Additionally, once a method of use of a compound is known it is within the skill of the artisan to determine the optimum dosage and frequency of administration.

Appellants close by arguing that a showing was not necessary because the Examiner failed to set forth a prima facie case of obviousness and that the state of the art does not support the conclusions drawn by the Examiner regarding Broder et al. This is not persuasive for the reasons set forth above.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Rebecca Cook
Primary Examiner
Art Unit 1614

November 30, 2003

Conferees

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

12/1/03

Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315